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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,454	02/02/2001	Gregorio del Val	2001-0705	9327

20872 7590 05/14/2004  
MORRISON & FOERSTER LLP  
425 MARKET STREET  
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/776,454

Applicant(s)

VAL ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/2/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-8, 10, 12, 22-25, 27-35 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10, 12, 22-25, 27-35, 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/3/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 1-4, 6-8, 10, 12, 22-25, 27-35, and 37-41 are pending.

Upon further consideration, the indicated allowability of claims 1, 2, 6-8, 10, 12, 22, 23, 27-33, 37-41 is withdrawn in view of the new 112 first paragraph written description rejection.

Rejections based on the newly 112 first paragraph written description follow.

Applicants' traversal and the amendment to claim 12 filed on 3/2/04 is acknowledged and considered.

### ***Claim Objections***

Claims 1-4, 6-8, 10, 22-25, 27-35 and 37-41 are objected to because of the following informalities: In view of the revised amendment practice 37 CFR 1.121 (Effective July 30, 2003) the status of the claims is improper. Suggest correcting the status as (previously presented).

Appropriate correction is required.

When filing the amendment to this instant action, applicants are reminded to follow the revised amendment practice 37 CFR 1.121. See 68 Fed. Reg. 38611 (June 30, 2003) or website <http://www.uspto.gov/web/patents/ifw/>.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 4, 6, 7, 8, 10, 12, 22, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, 34, 35, 37, 38, 39, 40, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 1, 22, and 32 filed on 2/21/03 introduced new subject matter into the application. The application and the originally filed claim as a whole are directed to:

A method for testing the allergenicity of a heterologous protein produced by a plant or animal that has been genetically modified to produce that protein, comprising the steps of:

- (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant or animal and containing a mixture of plant or animal proteins and the heterologous protein, by injecting, feeding or applying the extract to the skin of a newborn dog,
- (b) after a period sufficient to allow the dog to establish an immune response to the sensitizing extract, challenging the dog with the extract,
- (c) observing the degree of allergic response provoked,
- (d) if a detectable skin reaction is observed, comparing the degree of skin reaction observed with that observed by carrying out steps (a)-(c) above, but where

the sensitizing step (a) or applying step (b) is carried out with a second plant or animal extract containing substantially the same proteins as the first extract but lacking the heterologous protein, and  
(e) if the degree of skin reaction at (c) is greater than that observed by carrying out steps (a)-(c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans.

The original specification did not disclose using the dog from the first part of the method (steps a-c) in the second part of the method (steps d-g). As set forth above, the originally filed claims are directed to using a different dog in each part of the method. The working examples in the specification are directed to using a dog in a method of sensitizing and challenging and does not contemplate or recite the second part of claimed method of using the same dog in both parts of the originally filed claims. It is apparent that the applicants at the time the invention was made did not intend or contemplate using the same dog in both parts of the claimed method as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of using the same dog in both parts of the method set forth in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Claims 3, 4, 24, 25, 34, and 35 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 3, 24, and 34 filed on 2/21/03 introduced new subject matter into the application. The application and the originally filed claim as a whole are directed to a method of testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein comprising using a first extract comprising a mixture of plant proteins and the heterologous protein and a second extract comprising the same proteins as the first extract, but lacking the heterologous protein.

The original specification did not disclose using a second extract obtained from a genetically modified plant in the challenging step. The specification recites, “in a preferred embodiment, the extract is obtained from a transgenic plant (page 5, lines 24-25)” and “The second type of extract is prepared from tissue of a genetically modified plant or animal and contains a mixture of plant or animal proteins (page 12, B1. Sensitizing, lines 30-34).” It is apparent that the applicants at the time the invention was made did not intend or contemplate using a second extract obtained from a genetically modified plant in the challenging step as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of using a second extract obtained from a genetically modified plant in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicant's arguments filed 7/21/03 have been fully considered but they are not persuasive.

Applicants' argue that, "support for the amendment may be found throughout the specification. An example is on page 12, lines 30-33. "ii. Control substance/extract: The second type of extract is prepared from tissue of a genetically modified plant or animal and contains a mixture of plant or animal proteins."

With respect to applicants' argument, the argument is not found persuasive because the page cited for support of the amendment is directed to step for sensitizing the dog with a first and second extract and not the challenging step. Therefore, nothing in the specification would lead one to the particular combination set forth in the amended claims. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

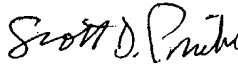
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER